Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0707888	04/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Alfred B Rosenstein Md	4000 Old Court Road Suite 205, Baltimore, MD	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of proficiency testing records, interview with the testing person, and the technical consultant, the laboratory did have all documents obtained during proficiency testing (PT). Findings: 1. American Association of Bioanalysts 2019 1st event hematology, the laboratory did not have the attestation nor the raw data. 2. American Association of Bioanalysts 2018 3rd event microbiology and hematology, the laboratory did not have the attestation nor the raw data. 3. American Association of Bioanalysts 2018 2nd event microbiology and hematology , the laboratory did not have the attestation nor the raw data. 4. American Association of Bioanalysts 2017 3rd event microbiology, the laboratory did not have the attestation. 5. American Association of Bioanalysts 2017 2nd event hematology, the laboratory did not have the attestation nor the raw data.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)

	(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of proficiency testing data, interview with the technical consultant and the testing person, the laboratory failed to successfully participate in the American Associates of Bioanalyst program for hematology testing, in which the laboratory is certified under CLIA. Findings: The laboratory failed the American Association of Bioanalysts 2019 1st event microbiology score 40%.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the written procedure manual, interview with the technical consultant (TC), and the testing person (TP), the laboratory did not have written procedures for all examinations performed by laboratory personnel. Findings: 1. The laboratory did not have step by step instructions for TP to follow for holding patient specimens when the hematology analyzer did not meet the laboratory's criteria of acceptability. 2. January 23, 2019 the hematology analyzer startup failed 18 times. The analyzer print out displayed " start up failed, check reagents" service was scheduled and patient testing was not performed. 3. The TP stated that patient samples were held until the analyzer was functioning properly and testing was resumed when service was performed by the manufacturer the next day on 1/24/19.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of the hematology quality control (QC) results, interview with the testing person (TP), and the technical consultant (TC), the laboratory did not ensure that hematology QC meet the laboratory's criteria of acceptability prior to performing testing patients. Findings: 1. The hematology "Quality Control" procedure states that controls must be acceptable and in range prior to patient results released and if controls are out of range start troubleshooting procedures. Steps include remix the QC, ensure that QC is not expired and rerun, open new QC if values are still unacceptable, perform a cleaning of the analyzer and rerun QC, contact the TC, and when needed if QC is still unacceptable contact technical support. 2. March 7, 2019 the TP stated that she did not run QC. The QC was ran by the shared lab personnel. 3. March 5, 2019 the laboratory was unable to locate the low level QC. The TP stated that she was unsure if she ran QC on that day or if the shared lab personnel ran the QC. 4. January 22, 2019 the hematology analyzer failed the startup and QC was not ran. The LD approved for patient testing to be performed and results released. 5. January 26, 2018 all three levels of QC was not within acceptable range for hemoglobin. The TP did not run the QC. The QC was ran by the shared laboratory personnel. Troubleshooting procedures were not performed by the TP. 6. January 25, 2018 the TP did not run the QC. The QC was performed by the shared laboratory personnel. Two out of the three levels of QC was not within the acceptable range. Troubleshooting procedures were not performed by the TP. Patient testing was performed and results were released. 7. January 5, 2018 the TP did not run QC. The QC was ran by the shared lab personnel. The TP initialed the QC because she didn't know who performed the QC. 8. April 16, 2018 The TP did not run QC. The QC was ran by the shared lab personnel. Two out of three levels of QC was not within acceptable range. Troubleshooting procedures were not performed by the TP. Patient testing was performed and results released. 9. April 10, 2018 two out of three levels of QC was not within acceptable range. Troubleshooting procedures were not performed by the TP. The LD approved the QC acceptable. Patients were tested and results released. 10. July 31, 2018 QC was not performed by the TP. The QC was performed by the shared lab personnel. The note on the printed QC record stated that the person running QC was not aware that when QC is out patient testing should not be performed. 11. July 23, 2018 two out of three levels QC was not within acceptable range. Troubleshooting procedures were not performed by the TP. The LD approved the QC acceptable. Patients were tested and results released. 12. July 28 and 31, 2018 two of the three levels of QC was not within acceptable range. Troubleshooting procedures were not performed by the TP. 13. July 21, 2018 the TP did not run QC. The QC was ran by the shared lab personnel. One out of the three levels of QC was not within acceptable range. Troubleshooting procedures were not performed by the TP. Patient testing was performed and results released. 14. October 11, 2018 two out of three levels of QC was not within acceptable range. Troubleshooting procedures were not performed by the TP. The LD approved the QC acceptable. Patients were tested and results released. 15. October 9, 2018 two out of three levels of QC was not within acceptable range. Troubleshooting procedures were not performed by the TP. The LD approved the QC acceptable. Patients were tested and results released.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of proficiency testing records, interview with the testing person, and the technical consultant, the laboratory director failed to maintain all documents obtained during proficiency testing (Refer to D2015); And Based on review of the written procedure manual, interview with the technical consultant, and the testing person, the laboratory director failed to have written procedures for all examinations performed by laboratory personnel (Refer to D5401).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that PT results were reviewed to identify problems and signed. Findings: 1. The LD signed the performance evaluation for the American Association of Bioanalysts 2nd event hematology in October 2018, five months after results were received form the PT agency. 2. The laboratory did not have the performance evaluation for the American Association of Bioanalysts 2017 3rd event microbiology. 3. The TC confirmed that the American Association of Bioanalysts 2nd event hematology in October 2018 was signed five months after results were received form the PT agency and that the 2017 3rd event microbiology performance evaluation was not available.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that corrective action procedures were performed for failed PT scores. Finding: 1. The laboratory failed the American Association of Bioanalysts 2019 1st event microbiology score 40%. 2. The LD did not have corrective action procedures for the failed results. 3. The TC confirmed that corrective action procedures were not performed for the American Association of Bioanalysts 2019 1st event microbiology score 40%.

D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of the hematology quality control results, interview with the testing person, and the technical consultant, the technical consultant failed to ensure that hematology QC meet the laboratory's criteria of acceptability prior to testing patients (Refer to D5481)
D6038	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(a) The technical consultant must be accessible to the laboratory to provide on-site, telephone, or electronic consultation. This STANDARD is not met as evidenced by: Based on review of the hematology quality control records, interview with the laboratory director, and the testing person (TP), the technical consultant(TC) could not be reached by phone when problems occurred in the laboratory and was not available on site to provide technical consultation. Findings: Refer to D5481 1. The laboratory director stated that the TC does not return phone calls when the they encounter problems in the lab and that the TC does not come on sight once a month. 2. The TP stated that when she calls the TC she may or may not receive a return call to assist with QC problems.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of hematology quality control (QC) records, interview with the technical consultant (TC), and the testing person, the TC failed to ensure that laboratory personnel followed QC procedures through out the analytic process of performing patient samples. Findings: Refer to D5481 I 1. The TC failed to ensure that hematology QC meet the laboratory's criteria of acceptability prior to performing patient testing. 2. On January 23, 2019 the hematology analyzer startup failed 18 times. The analyzer print out displayed "startup failed, check reagents" service was scheduled and patient testing was not performed. The TP states that she was not at work on 1/23/19 but signed the QC when she returned because the initials of the TP was not on the QC documents. 3. The hematology analyzer was serviced on 1/24/19 the startup passed and the precision failed for the white blood cells. Patient testing

	was performed on the analyzer. 4. On July 31, 2018 QC was not performed by the TP. The QC was performed by the shared lab personnel. The note on the printed QC record stated that the person running QC was not aware that when QC is out patient testing should not be performed. II Based on review of the hematology quality control (QC) procedure, interview with the technical consultant (TC), and the testing person (TP), the TC failed to ensure that laboratory personnel performed the "new control" procedure when performing hematology testing. Findings: 1. The hematology "new control" procedure states that prior to the current QC expiring. Run a new set of all three levels of QC. 2. Compare the results to the package insert and ensure that all three levels of QC are in range. Maintain the printout from the analyzer along with the package insert. 3. Change the old QC lot number to the new QC lot number prior to the old lot expiring and print the old QC lot numbers that are store in the analyzer. 4. Print the Levy-Jennings charts that are collected for the old QC with the previous lot numbers and remove the old QC smart card form the analyzer. Once the old QC smart card is removed replace with the new QC smart card. 5. All QC logs and Levy-Jennings charts should be faxed to the TC. 6. The TC stated during the interview at the time of the survey around 1:00 PM that she does not review Levy-Jennings charts.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on review of the hematology quality control (QC) procedure, interview with the technical consultant (TC), and the testing person (TP), the TC failed to ensure that remedial action procedures were performed when the QC did not meet the laboratory's criteria of acceptability when performing hematology testing. Findings: Refer to D5481 The hematology "Quality Control" procedure states that controls must be acceptable and in range prior to patient results released and if controls are out of range start troubleshooting procedures. Steps include remix the QC, ensure that QC is not expired, and rerun, open new QC if values are still unacceptable, perform a cleaning of the analyzer and rerun QC, contact the TC, and when needed if QC is still unacceptable contact technical support.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on review of the hematology quality control (QC) procedure, interview with the technical consultant (TC), and the testing person (TP), the TC failed to ensure that corrective action procedures were performed when the QC did not meet the laboratory's criteria of acceptability when performing hematology testing. Findings: Refer to D5481 1. The laboratory did not document corrective action procedures when hematology QC was not within acceptable range prior to performing patient testing. 2.

	The hematology "Quality Control" procedure states that controls must be acceptable and in range prior to patient results released and if controls are out of range start troubleshooting procedures. Steps include remix the QC, ensure that QC is not expired, and rerun, open new QC if values are still unacceptable, perform a cleaning of the analyzer and rerun QC, contact the TC, and when needed if QC is still unacceptable contact technical support.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of training records and interview with the technical consultant (TC), the TC did not document observation procedures performed for the new testing person when performing hematology testing. Findings: 1. The laboratory hired a new testing person that began hematology testing during the year 2018. 2. The TC did not have the testing person (TP) diploma on file and observations of training skills were not performed prior to the TP performing patient testing. 3. The TC stated that she was unable to find the training records for the new laboratory testing person.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of the hematology quality control (QC) procedure, interview with the technical consultant (TC), and the testing person (TP), the TP failed to perform the "new control" procedure when performing hematology testing. Findings: 1. The hematology "new control" procedure states that prior to the current QC expiring. Run a new set of all three levels of QC. 2. Compare the results to the package insert and ensure that all three levels of QC are in range. Maintain the printout from the analyzer along with the package insert. 3. Change the old QC lot number to the new QC lot number prior to the old lot expiring and print the old QC lot numbers that are store in the analyzer. 4. Print the Levy-Jennings charts that are collected for the old QC with the previous lot numbers and remove the old QC smart card form the analyzer. Once the old QC smart card is removed replace with the new QC smart card. 5. All QC logs and Levy-Jennings charts should be faxed to the TC. 6. The TC stated during the interview at the time of the survey around 1:00 PM that she does not review Levy-Jennings charts.
D6073	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(4) Each individual performing moderate complexity testing must follow the laboratory's established corrective action policies and procedures whenever test systems are not

	within the laboratory's established acceptable levels of performance. This STANDARD is not met as evidenced by: Based on review of the hematology quality control (QC) procedure, interview with the technical consultant (TC), and the testing person (TP), the TP failed to follow corrective action procedures when the QC did not meet the laboratory's criteria of acceptability when performing hematology testing. Findings: Refer to D5481 1. The TP did not document corrective action procedures when QC was not within acceptable range when performing hematology testing. 2. The hematology "Quality Control" procedure states that controls must be acceptable and in range prior to patient results released and if controls are out of range start troubleshooting procedures. Steps include remix the QC, ensure that QC is not expired, and rerun, open new QC if values are still unacceptable, perform a cleaning of the analyzer and rerun QC, contact the TC, and when needed if QC is still unacceptable contact technical support.